510(K) SUMMARY

AMO Brand
Multi-Purpose Disinfecting Solution

This summary used the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

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(a)(2) **Device Trade Name:** AMO Brand Multi-Purpose Disinfecting Solution

Device Common Name: Soft (Hydrophilic) Contact Lens Solution

Device Classification/Panel: Class II (Special Controls)/Ophthalmic Device

Device Classification Names: Accessories to Contact Lens Solution (86LPN)

(a)(3) **Identification of Predicate Device:**

AMO Brand Multi-Purpose Disinfecting Solution (MPDS 9608X) is substantially equivalent to ALCON® Opti-free® RepleniSH® Multi-purpose disinfecting solution.

(a)(4) **Device Description:**

AMO Brand Multi-Purpose Disinfecting Solution is a sterile and buffered aqueous solution containing disinfectants / preservatives, buffers, a surfactant, a chelating agent, other ancillary agents, and purified water. The solution is packaged in tamper-resistant multi-dose plastic bottles with controlled dropper tips.

(a)(5) **Intended Use (Indications for Use)**

AMO Brand Multi-Purpose Disinfecting Solution is indicated for the care of soft (hydrophilic) contact lenses, including silicone hydrogel lenses. Use this product as recommended by your eye care practitioner to:

- Chemically (NOT HEAT) Disinfect
- Clean

- Rinse
- Store
- Remove Protein
- Condition

(a)(6) **Comparison of Technological Characteristics**

The technological characteristics of the new formulation remain the same as the predicate device.

(b)(1) **Discussion of Non-Clinical Testing**

Solution Compatibility: AMO Brand Multi-Purpose Disinfecting Solution was tested for compatibility with conventional Group 1 and Group 4 soft (hydrophilic) contact lenses, and with four (4) representative marketed silicone hydrogel lenses. The results demonstrate the product is compatible with soft contact lenses, including silicone hydrogel lenses. The tests were primarily carried out in accordance with the FDA Guidelines, Premarket Notification (510(k)) Guidance Documents for Contact Lens Care Products, May 1, 1997.

Protein Removal: AMO Brand Multi-Purpose Disinfecting Solution and the predicate device were tested for their abilities to remove lysozyme protein on contact lens surfaces. AMO® Brand Multi-Purpose Disinfecting Solution demonstrated its ability to passively and effectively remove protein from soft (hydrophilic) contact lenses, including silicone hydrogels, which is comparable to the predicate device.

Wettability of Contact Lenses: The contact angles of water drops on contact lenses were measured using the sessile drop method. Contact lenses, including four (4) representative silicone hydrogel contact lenses and FDA Group IV contact lenses, were presoaked in MPDS 9608X, or the predicate device, Opti-Free® RepleniSH®. The results demonstrate AMO® Brand Multi-Purpose Disinfecting Solution and Opti-Free® RepleniSH® are equivalent in soft (hydrophilic) contact lens, including silicone hydrogels, wettability, conditioning, and moisturizing.

Microbiological Studies: The product was evaluated for microbiological efficacy using studies outlined in FDA's Premarket Notification (510(k)) Guidance Documents for Contact Lens Care Products, May 1, 1997, modified to include organic soil in the stand alone test and test solution formulated to the low specification of the disinfectants / preservatives.

- The product meets current FDA requirements for disinfection of contact lenses against bacteria, yeast, and mold at low shelf specifications for the disinfectant / preservative system.
- AMO brand Multi-Purpose Disinfecting Solution is formulated with dual-disinfection technology designed specifically for soft contact lenses, including silicone hydrogel lenses. Dual disinfectants work to destroy microbes on the surface of the lens and provide safe contact lens storage up to 30-days. All

tests used AMO® Brand Multi-Purpose Disinfecting Solution at the low shelf specifications for the disinfectant / preservative system.

- The product meets USP <71> sterility test requirements.

Stability: Accelerated testing indicates AMO Brand Multi-Purpose Disinfecting Solution will remain stable for the labeled shelf-life.

Biocompatibility: The safety of the product was evaluated with a worst case formulation at the upper specification for the disinfectants / preservatives using studies outlined in the FDA's Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997 and Pre-IDE I080487 Investigational Multi-Purpose Solution for Contact Lens Care, July 31, 2008.

- Cytotoxicity: Neither the test formulation, nor the predicate device, were cytotoxic to mouse fibroblasts cells after 24 hours.
- Sensitization: There were no dermal reactions from either test or control.
- Ocular irritation: 1-day acute ocular irritation study in rabbits demonstrated no ocular irritation.
- 22-day Ocular Safety Studies with Contact Lenses: Treatment with either the test formulation or control with either PureVision™ or Acuvue® 2 contact lenses was well tolerated in rabbits over the indicated period of time.
- Acute Oral Toxicity: Neither the test formulation or the control caused an adverse effect when administered to rats in a single oral dose.
- Cytotoxicity with pre-soaked contact lenses – Direct Contact. Overall results showed MPDS 9608X was less cytotoxic than the predicate device.

(b)(2) **Discussion of Clinical Data:**

A multi-center clinical trial was conducted using AMO Brand Multi-Purpose Disinfecting Solution. The safety and performance of the product were evaluated in soft contact lenses, including silicone hydrogel lens wearers. It was demonstrated the product is safe and effective when using soft (hydrophilic) contact lenses, including currently marketed silicone hydrogel lenses.

An additional single-center clinical trial was conducted using AMO Brand Multi-Purpose Disinfecting Solution. The safety and performance of the product were evaluated in PureVision™ lenses at specified time points over a period of four days. It was demonstrated that the product is comparable to the predicate device in terms of patient acceptability, lens wearing comfort, and corneal staining.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination**

It is concluded that the safety, efficacy, and performance of AMO Brand Multi-Purpose Disinfecting Solution is substantially equivalent to the predicate device, ALCON® Opti-Free® RepleniSH®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Abbott Medical Optics, Inc.
c/o Ms. Kesley E. Gallagher
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SEP 15 2010

Re: K093254
Trade/Device Name: AMO brand Multi-Purpose Disinfecting Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: July 29, 2010
Received: July 30, 2010

Dear Ms. Gallagher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER:
(IF KNOWN) K093254

DEVICE NAME: AMO brand Multipurpose Disinfecting Solution

INDICATIONS FOR USE:

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- Clean
- Rinse
- Store
- Remove Protein
- Condition

SEP 15 2010

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use___
(Per 21 CFR 801.109)

OR K. Watanabe Over-the-Counter-Use ✓
(Division Sign-Off) (Optional Format 1-2-96)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K093254